

# UNITED STATES PATENT AND TRADEMARK OFFICE

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09/202,634	03/03/1999	ROLAND SCHUBERT	9725.13-US-W	3169
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MERCHAN7	C& GOULD PC		EXAMI	NER
P.O. BOX 2903			EINSMANN, JULIET CAROLINE	
MINNEAPOL	IS, MN 55402-0903		Bittom It it, Jobbs Cities	
			ART UNIT	PAPER NUMBER
			1634	24
			DATE MAILED: 10/17/2002	$\omega$

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		09/202,634	SCHUBERT ET AL.				
		Examiner	Art Unit				
		Juliet C Einsmann	1634				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status 1)⊠							
<u> </u>	This action is <b>FINAL</b> . 2b) This action is non-final.						
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>							
-	Claim(s) <u>1-4,8-11,15,18-21,23,27,33 and 38-4</u>	4 is/are pending in the application	on.				
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
, —	Claim(s) <u>1-4,8-11,15,18-21,23,27,33 and 38-44</u> is/are rejected.						
	Claim(s) 8-10,27,33 and 44 is/are objected to.						
, —	8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10)⊠ The drawing(s) filed on <u>03 March 1999</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)[∑	All b) Some * c) None of:						
	<ol> <li>Certified copies of the priority document</li> </ol>	s have been received.					
:	2. Certified copies of the priority document	s have been received in Applica	tion No				
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)							

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#### **DETAILED ACTION**

1. This action is written in response applicant's correspondence submitted 7/5/02 and 8/7/02, papers number 21 and 22. Claims 1-4, 8-11, 15, 18-21, 23, 27, and 33 have been amended, claims 5-7, 12-14, 16, 17, 22, 24-26, 28-32, and 34-37 have been canceled, and claims 38-44 have been added. Claims 1-4, 8-11, 15, 18-21, 23, 27, 33, and 38-44 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.** 

## **Drawings**

2. New corrected drawings are required in this application in accordance with the PTO 948 mailed with paper number 19. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance (see 37 CFR 1.85(a)).

#### Claim Objections

3. Claims 8, 9, 10, 27, 33, and 44 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8 and 9 are not properly dependent because they do not require all of the limitations of claim 4 since the nucleic acid

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molecule of claim 8 can be that as set forth in claim 4, or "an ozone inducible fragment thereof." Thus, the "fragment" language of claim 8 broadens the claim so as not to include all of the limitations of claim 4 from which claims 8 and 9 depend. Claims 10, 27, 33, and 44 are objected to for analogous reasons over the recitation of "or fragments thereof" and/or "or a fragment thereof."

4. Claim 39 is objected to because there is a period after the word "tuber" in the middle of the claim. Claim 42 is objected to because it does not end in a period. MPEP 601.01(m) states, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations."

### Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 1, 3, 15, 18, 23, 27, 33, 42, 43, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation "comprising of the sequence" because it is not clear what it means to be "comprising of" a sequence. Deletion of the word "of" will obviate this rejection.

Claim 1 is indefinite because the limitations appear to conflict with one another. First the claim sets forth "An isolated nucleic acid comprising of the sequence...(SEQ ID NO: 1)," but then the claim also recites "as set forth in claim 4." The first part of the claim requires the presence of SEQ ID NO: 1 in its entirety, but claim 4 does not require SEQ ID NO: 1, merely

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sequences with homology to SEQ ID NO: 1 or variants of SEQ ID NO: 1. Thus, the scope of claim 1 is unclear because it is unclear how the "as set forth in claim 4" portion of claim 1 relates to the preceding portion of the claim. Deletion of the language "as set forth in claim 1" would obviate this rejection.

Claim 3 is indefinite over the recitation "and corresponds to base pairs -270 to -430" because it is not clear what sequence these numbers are referencing. Amendment of this claim to instead recite a particular sequence identifier would obviate this rejection.

In claim 15, it is not clear what applicant intends by "wherein said nucleic acid sequence does not naturally occur." It is not clear if applicant is trying to delineate that fragments consisting of SEQ ID NO: 1 do not naturally occur, or if applicant is limiting the claim to exclude any nucleic acid sequence which is within the scope of claim 4 but also occurs within larger sequences in nature (i.e. limiting the claim to include only non-naturally occurring derivatives of SEQ ID NO: 1). Claim 18 is indefinite because it depends from claim 15 and does not clarify this issue. Claim 23 is also indefinite over the recitation "wherein said nucleic acid sequence does not naturally occur."

Claims 27, 43, and 44 indefinite because it does not clearly set forth how the introduction of the nucleic acid of claim 4 would result in one or several genes becoming ozone inducible due to the introduction of the nucleic acid of claim 4. Thus, it is not clear how the introduction of the sequence of claim 4 has the desired effect. The fact that the nucleic acid of claim 4 is linked to the genes that become inducible is a critical limitation of this method. Furthermore, claim 44 is indefinite over the recitation "wherein the one or several genes are ozone-inducible reporter genes" because this appears to conflict with claim 27 which recites that

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the genes "are not naturally or substantially induced by ozone." Amendment of claim 44 to recite "wherein the one or several genes are reporter genes" would clarify this matter.

Claim 33 is indefinite because the preamble of the claim recites "a method for producing ozone-inducible characteristics in transgenic plants or plant cells" but the only method step in the claim recites inserting the DNA sequence as set forth in claim 4 into those genes which are not naturally or substantially inducible through ozone. The claim does not make a connection between the making of transgenic plants or cells and the insertion of the DNA sequence of claim 4 into genes.

Claim 42 is an incomplete claim because it recites a preamble, but no limitation. The claim reads "A plant as set froth in claim 41,".

## Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 8. Claims 1, 2, 3, 4, 8, 9, 10, 11, 15, 18, 19, 20, 21, 23, 27, 33, and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to plant DNA sequences, transgenic plants comprising said sequences, or methods of transformation of the transgenic plants. Each of the rejected claims recites modification of the sequence provided in SEQ ID NO: 1 by homology language, by the

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inclusion of "naturally occurring or artificially introduced variations" or the claim require only that a fragment of SEQ ID NO: 1 be present or utilized.

Instant SEQ ID NO: 1 is a portion of the V. vinifera Vst1 gene promoter which applicant has identified as being essential for the promoter to mediate the induction of heterologous genes via ozone. Applicant has not provided any examples of shorter fragments of SEQ ID NO: 1 that still retain the function of SEQ ID NO: 1. The claims encompass variants and fragments of SEQ ID NO: 1 that "convey ozone-inducible expression," yet the specification has not provided written description of any variants or fragments of SEQ ID NO: 1 that convey this property.

Instead, the specification recites that SEQ ID NO: 1 is essential for a promoter to mediate the induction of genes via ozone. Essentially, claim 4 encompasses any possible DNA sequence which is able to convey ozone-inducible gene expression because the language of the claim provides no required structure for the claimed promoter since the number and type of allowed changes is unlimited. This large genus is represented in the specification by one species, SEQ ID NO: 1. Thus, applicant has express possession of only one species in a genus which comprises hundreds of millions of different possibilities.

Claims 15, 18 and 23 specifically recite sequences do "not naturally occur," but convey ozone-inducible gene expression. If this limitation intends exclude any nucleic acid sequence which is within the scope of claim 4 but also occurs within larger sequences in nature, then the specification has not provided a single example within this genus. Instant SEQ ID NO: 1 is a naturally occurring nucleic acid sequence, and it is the singular example in the specification of a sequence that conveys ozone-inducible gene expression. Thus, there is no written description in

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the specification to support the transgenic plants and plant parts encompassed within claims 15, 18, and 23.

All of these claims encompass nucleic acid sequences different from those disclosed as SEQ ID No: 1 which, for claims 4 includes modifications by permitted by the % identity language for which no written description is provided in the specification. In promoter sequences, there is often little or no homology between sequences which retain the same function. For example, Guiltinan *et al.* teach that "it is known that 5' and 3' regulatory regions of genes, while often sharing overall functional similarities, do not share a high degree of sequence homology (sentence bridging pages 19-20)."

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequence of the disclosed SEQ ID Nos are described. Also, in <u>Vas-Cath Inc. v. Mahurkar</u> (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any proteins modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 1 but possessing one or more nucleic acid differences

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such that a different nucleic acid sequence would have the ability to regulate ozone-inducible expression of transgenes.

### Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1-4, 8, 9, 10, 11, 15, 18, 19, 21, 23, 27, 33, 35, 36, 38, 39, 40, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (1994, Dissertation, "Optimierung der heterologen Expression von Stilbensynthasegegen für den Pflnzenschutz" Institut für Biotechnologie, Universität Hohenheim).

Fischer teaches a plant DNA sequence which is the promoter for the Vitis vinifera Vst1 promoter (p. 152-153). The promoter taught by Fischer is an isolated nucleic acid comprising SEQ ID NO: 1 (see p. 152 of Fischer, the sequence at nucleotides 2555-2716). Fischer further teaches vectors which contain SEQ ID NO: 1, as well as transgenic tobacco plants which contain the vectors comprising SEQ ID NO: 1 (section 3.3.1).

It is noted that Fischer does not specifically teach that ozone-inducible gene expression of a gene that does not naturally occur can take place in these plants, however this is an inherent property of the plants transformed with the vectors taught by Fischer, wherein the vector is driving the expression of a reporter gene. Fischer further teaches methods for making such plants. Applicant is reminded that "The claiming of a new use, new function or unknown

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property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112)."

### Claim Rejections - 35 USC § 103

- 11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher in view of Logemann *et al.* (US 5689045).

Fischer teaches a plant DNA sequence which is the promoter for the Vitis vinifera Vst1 promoter (p. 152-153). The promoter taught by Fischer comprises instant SEQ ID NO: 1 (the nucleic acid recited in claim 1 is instant SEQ ID NO: 1). Fischer further teaches vectors which contain SEQ ID NO: 1, as well as transgenic tobacco plants which contain the vectors comprising SEQ ID NO: 1 (section 3.3.1). It is noted that Fischer does not specifically teach that ozone-inducible gene expression of a gene that does not naturally occur can take place in these

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plants, however this is an inherent property of the plants transformed with the vectors taught by Fischer, wherein the vector is driving the expression of a reporter gene. Fischer further teaches methods for making such plants. Fischer teaches that the promoter utilized in their methodology is pathogen responsive, particularly responsive to *B. cinerea*.

Fisher does not teach monocot plants.

Logemann et al. transgenic plants that are pathogen-resistant, particularly plants that are the monocot corn (Col. 5, lines 38-42, for example). Logemann et al. teach the transgenic plants of their invention demonstrate resistance to the fungus Botrytis (Col. 3, line 10). Logemann et al. further teach that the promoter used in the transformation construct can be a pathogen-inducible promoter (Col. 4, lines 49).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods and products taught by Fischer with those taught by Logemann *et al.* in order to have provided monocot plants which comprise the promoters taught by Fisher. The ordinary practitioner would have been motivated to produce such plants in order to have provided monocot plants with increased resistance to the fungal pathogen Botrytis which is known to attack a wide range of plants, including many monocots.

14. Claims 20, 41, and 42 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher in view of Conkling et al. (US 5750386).

Fischer teaches a plant DNA sequence which is the promoter for the Vitis vinifera Vst1 promoter (p. 152-153). The promoter taught by Fischer comprises instant SEQ ID NO: 1 (the nucleic acid recited in claim 1 is instant SEQ ID NO: 1). Fischer further teaches vectors which contain SEQ ID NO: 1, as well as transgenic tobacco plants which contain the vectors

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comprising SEQ ID NO: 1 (section 3.3.1). It is noted that Fischer does not specifically teach that ozone-inducible gene expression of a gene that does not naturally occur can take place in these plants, however this is an inherent property of the plants transformed with the vectors taught by Fischer, wherein the vector is driving the expression of a reporter gene. Fischer further teaches methods for making such plants. Fischer teaches that the promoter utilized in their methodology is pathogen responsive, particularly responsive to *B. cinerea*.

Fisher does not teach monocot plants, and in particular, do not teach the transformation of grains.

Conkling *et al.* transgenic plants that are pathogen-resistant, and particularly that monocots such as wheat, oats, rice and barley are within the scope of their teachings (Col. 8, lines 49-50). Conkling *et al.* teach the transgenic plants of their invention demonstrate resistance to the fungus Botrytis (Col. 10, line 54). Conkling *et al.* further teach that the promoter used in the transformation construct can be a pathogen-inducible promoter (Col. 3, line 44-Col. 4, line 6).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods and products taught by Fischer with those taught by Conkling *et al.* in order to have provided monocot plants which comprise the promoters taught by Fisher. The ordinary practitioner would have been motivated to produce such plants in order to have provided monocot plants with increased resistance to the fungal pathogen Botrytis which is known to attack a wide range of plants, including many monocots.

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#### Response to Remarks

- Applicant requested withdrawal of the claim objections in light of the amendments to the claims, wherein claim 4 was made independent and claims 8, 9, 10, 27-29, and 33 were amended to depend from claim 4. However, the rejection is reiterated for claims 8, 9, 10, 27, 33, and 44 for the reasons discussed in the objection. Essentially, applicant's amendment failed to remedy the fact that these claims do not require all of the limitations of the independent claim from which they depend.
- Applicant asserts forth that the specific 112 2<sup>nd</sup> rejections of the previous office action were addressed by amendment or argument. This is persuasive to overcome all of the previous 112 2<sup>nd</sup> rejections except that to claim 3 which was neither addressed by amendment or traversed. Thus, this rejection is maintained, and new 112 2<sup>nd</sup> paragraph rejections are set forth based on the amendments to the claims.
- 17. Applicant points out that the specification has disclosed that fragments shorter than instant SEQ ID NO: 1 that retain function as an ozone-inducible promoter are contemplated, specifically referencing a number of portions of the specification. However, this is not persuasive to overcome the rejection under written description. Applicant has stated in the specification that instant SEQ ID NO: 1 is "essential for the ozone-induced gene expression in plants (p. 8, line 2)." Furthermore, at page 12, the last paragraph, which Applicant cites in the response, the specification teaches that the deletion of SEQ ID NO: 1, or "at least a fragment of such a sequence" from the V. vinifera Vst1 promoter results in the production of a promoter that is not induced by ozone. Herein, however, applicant claims a number of variants and sequences related to SEQ ID NO: 1 by homology which retain ozone-inducible activity, yet provides no

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examples or guidance as to the features within SEQ ID NO: 1 that must be present in order to retain this activity. Thus, although applicant's specification discusses the possibility of variants and fragments of SEQ ID NO: 1, the specification does not demonstrate possession of any ozone-inducible promoters besides instant SEQ ID NO: 1.

18. Applicants cite the IPER of the PCT application from which this application is based as evidence that the rejected claims are not anticipated by Fisher. However, it appears that the IPER is considering the instant invention in light of "closed" claim language. That is, a situation in which a fragment consisting of SEQ ID NO: 1 is claimed. This is not the case herein. Thus, applicant is arguing a feature which is not claimed.

The instant claims are drawn to a nucleic acid comprising SEQ ID NO: 1. The use of the open claim language "comprising" means that SEQ ID NO: 1 must be present, but can be flanked by additional sequences. The V. vinfera Vst1 promoter taught by Fisher thus, comprises SEQ ID NO: 1 (see p. 152 of Fischer, the sequence at nucleotides 2555-2716). Fisher teaches nucleic acid constructs which contain this sequence as well as transgenic tobacco plants that comprise these vectors (see the deletion analysis on page 90 of Fisher, wherein a number of chimeric molecules comprising SEQ ID NO: 1 are presented, i.e. at least the first six constructs listed in Table 11). The examiner does not disagree with the IPER that it cannot be concluded from Fisher that instant SEQ ID NO: 1 could be responsible for the ozone inducible expression of genes under the control of SEQ ID NO: 1. However, ozone inducibility is indeed an inherent property of the entire promoter taught by Fisher. Applicant is reminded that "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112)."

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An isolated nucleic acid consisting of SEQ ID NO: 1 is free of the prior art. However, constructs which **comprise** this sequence are not free of the prior art, as is evidenced by the art of record.

#### Conclusion

- 19. No claims are allowed.
- 20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Einsmann

Examiner

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October 7, 2002

Supervisory Patent Examiner Technology Center 1600